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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,445	06/21/2001	Robert H. Frater	P 279185 P95US1	2733

909 7590 01/15/2003

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EXAMINER

FERKO, KATHRYN P

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/885,445

Applicant(s)

FRATER ET AL.

Examiner

Kathryn Ferko

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-80 and 87-90 is/are pending in the application.
- 4a) Of the above claim(s) 1-22, 34-80 and 87-90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-22, 34-80 and 87-90 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 and 9. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Claims 1-22, 34-80, and 87-90 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group and Species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.
2. Applicant's election without traverse of claims 23-33 in Paper No. 10 is acknowledged.

Drawings

3. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "23" has been used to designate both baffle and air supply. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

5. The disclosure is objected to because of the following informalities: in the Brief Description of the Drawings section Figure 1 should be explicitly recite that it is of Prior Art. Additionally, any corresponding changes required to distinguish element 23 are required as well.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 23-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frater et al. (the current application disclosure of Prior Art such as that of Figure 1) in view of Tenna in US Patent No. 5,080,092 or Holloway in US Patent No. 3,545,436.

Frater et al. in the current application disclose a mask (110) for delivering breathable gas to a patient where the mask (110) has a shell (120) having a portion adapted to receive a supply of pressurized breathable gas and a user side, as seen in Figure 1; a cushion (130) constructed and arranged to contact a user's face in use and provide a seal between the mask and the user's face; and a headgear constructed and arranged to attach the mask shell to the user, as stated in Background section of the current disclosure.

However Frater et al. do not recite a gusset portion having a first side attached to the user side of the shell; a gusset portion that is constructed and arranged such that it can expand and contract within a range of displacement to alter a distance between the mask shell and the cushion where, the gusset portion defines a gusset area exposed to the supply of pressurized breathable gas in use such that the supply of pressurized breathable gas acting on the

gusset area provides a component of a contact force $F_{sub.c}$ of the cushion on the user's face, the force $F_{sub.c}$ being maintained in approximately constant proportion to the supply of pressurized breathable gas and a total force of the mask on the face F_m being maintained within a range of about 35-108 grams per gf/cm^2 pressure of the supply of pressurized breathable gas over an operating pressure range of the mask; a force F_m that is maintained within a range of about 40-88 grams per gf/cm^2 pressure of the supply of pressurized breathable gas; a force F_m that is maintained within a range of about 50-88 grams per gf/cm^2 pressure of the supply of pressurized breathable gas; an operating pressure range that is about 4-25 gf/cm^2 ; expansion and contraction of the gusset portion that permits a seal to be maintained between the cushion and the user's face within a range of about plus and minus 8 degrees angular displacement of the mask shell with respect to the user's face; a gusset portion that includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section when exposed to the supply of pressurized breathable gas; a gusset portion includes a sidewall having a thickened cross-section at a base of the sidewall, where the thickened cross-section has a generally uniform thickness; a gusset portion that includes a sidewall having a cross-sectional thickness tapering from a thickened base portion to a thinner portion; a generally rigid backstop attached to the mask shell for contacting a first sidewall portion of the gusset portion to limit movement of

the first sidewall portion; or a rigid backstop extends around substantially an entire periphery of the gusset portion.

On the other hand, both Holloway and Tenna teach of a gusset portion, (18) in Holloway and (15-17) in Tenna. In these masks, a first side of the gusset is attached to the user side of the shell. The a gusset portion is constructed and arranged such that it can expand and contract within a range of displacement to alter a distance between the mask shell where, the gusset portion defines a gusset area exposed to a supply of pressurized breathable gas (wherein any gas will have an associated pressure and is supplied from some type of a source) in use such that the supply of pressurized breathable gas acting on the gusset area provides a component of a contact force $F_{sub.c}$ of the cushion on the user's face, the force $F_{sub.c}$ being maintained in approximately constant proportion to the supply of pressurized breathable gas and a total force of the mask on the face F_m being maintained within a range. These masks also have a gusset portion that includes a single gusset having a flexible sidewall with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section when exposed to the supply of pressurized breathable gas, as seen in the figures.

Therefore, it would be obvious to one with ordinary skill in the art to modify the Prior Art discussed in the current application to interpose a gusset between the shell and the cushion for the purpose of increasing the seal capability and comfort level. Holloway discusses the gusset function in column 3, lines 7-23.

"The web 18 also flexes to accommodate the seal to a particular face.... The fit of the mask to the face of a user is extremely comfortable due to such hinged floating action." Tenna discusses the gusset function in column 2, lines 45-50. The gusset has a bellows section and guarantee "a perfect tightness face-mask and at the same time good comfort." Given this teaching it would be desirable to include a gusset section for they allow a good seal which is necessary due to patient movement and good comfort which is necessary for the patients to obtain a good sleep, in an application such as CPAP. Furthermore, it is within the scope of the addition of a gusset in the mask of the Prior Art to have requirements of about 35-108 grams per gf/cm^2 pressure of the supply of pressurized breathable gas over an operating pressure range of the mask; a force F_m that is maintained within a range of about 40-88 grams per gf/cm^2 pressure of the supply of pressurized breathable gas; a force F_m that is maintained within a range of about 50-88 grams per gf/cm^2 pressure of the supply of pressurized breathable gas; and an operating pressure range that is about 4-25 gf/cm^2 . Providing gussets will increase comfort and enhance the sealing capabilities so it would be obvious from the force equations that when the gussets are provided they will fall within the above ranges. Furthermore, expansion and contraction of the gusset portion that permits a seal to be maintained between the cushion and the user's face within a range of about plus and minus 8 degrees angular displacement of the mask shell with respect to the user's face; a gusset portion includes a sidewall having a thickened cross-section

at a base of the sidewall, where the thickened cross-section has a generally uniform thickness; a gusset portion that includes a sidewall having a cross-sectional thickness tapering from a thickened base portion to a thinner portion; a generally rigid backstop attached to the mask shell for contacting a first sidewall portion of the gusset portion to limit movement of the first sidewall portion; and a rigid backstop extends around substantially an entire periphery of the gusset portion are also within the scope of the invention as the way in which to incorporate the gusset while maintaining an optimal seal. It would be obvious that the seal be maintained within a certain degree as to maintain its placement and thickening the sidewalls is a known method of increasing reinforced attachments.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 4,402,316; US Patent No. 4,641,645; US Patent No. 4,905,683; US Patent No. 4,914,957; US Patent No. 5,299,448; US Patent No. 5,355,878; US Patent No. 5,503,147; US Patent No. 5,937,445; US Patent No. 6,019,101; US Patent No. 6,213,125; US Patent No. 6,328,031; US Patent No. 6,345,618; and US Patent No. 6,425,395.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Ferko whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

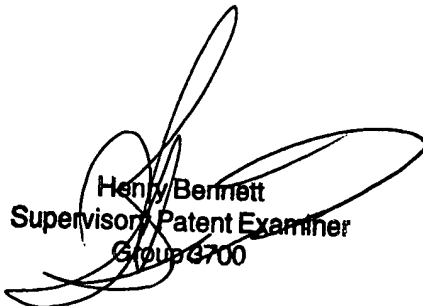
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KF
January 10, 2003



Henry A Bennett
Supervisor Patent Examiner
Group 3700